Guidance for Industry

Labeling OTC Human Drug Products Using a Column Format

DRAFT GUIDANCE

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register.*

For questions on the content of this draft document, contact Gerald M. Rachanow or Cazemiro R. Martin at 301-827-2222.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

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Draft - Not for Implementation

Guidance for Industry[1]

Labeling OTC Drug Products

Using a Column Format

I. INTRODUCTION

This guidance is intended to assist manufacturers, packers, and distributors who wish to present labeling information for their over-the-counter (OTC) drug products using a column format.

II. BACKGROUND

In the *Federal Register* of March 17, 1999 (64 FR 13254), the Food and Drug Administration (FDA) published a final regulation establishing standardized content requirements and a standardized format for the labeling of OTC drug products. Standardized labeling for OTC drug products is intended to make it easier for consumers to read and understand OTC drug product labeling and use OTC drug products safely and effectively.

The new labeling regulation in 21 CFR 201.66 covers all OTC drug and drug-cosmetic products, whether marketed under a new drug marketing application (NDA), abbreviated new drug application (ANDA), or OTC drug monograph (or product not yet the subject of a final OTC drug monograph).

Section 201.66(d)(5) of the labeling regulation provides that the "Drug Facts" labeling information may appear on more than one panel on the outside container of the retail package, or on the immediate container label if there is no outside container or wrapper. When continuing the required content and format information onto multiple panels, the required order and flow of headings, subheadings, and information must be maintained as well. The regulation also requires the use of a visual graphic (e.g., an arrow) to signal the continuation of the Drug Facts labeling to the next adjacent panel.

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[1]This guidance has been prepared by the Division of Over-the-Counter Drug Products in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration. This guidance document represents the Agency's current thinking on the presentation of required OTC drug labeling in a column format. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

The Agency has received a number of inquiries as to whether the required labeling information may be presented using a column format. One question raised in these inquiries is whether the required headings, subheadings, and text may be divided into columns ***within*** a single, defined Drug Facts box or enclosure, or whether such an approach would be inconsistent with the final rule. The final format for the Drug Facts box generally favors a vertical, linear presentation, to enhance readability and facilitate product comparisons. Except for the presentation of active ingredient and purpose information (see § 210.66(d)(6)) and the use of a table to present complex dosing information (see § 201.66(d)(9)), the final format does not allow required information to be separated into columns ***within*** a given Drug Facts box. However, the rule does allow for the use of an alternative column format that can help to maximize available labeling space and, in some instances, improve readability. Specifically, this guidance describes how more than one Drug Facts box or enclosure can appear on each side of a package or a container to allow for the use of columns.

III. COLUMNS UNDER THE STANDARD LABELING FORMAT

The format established under the regulation generally requires headings, subheadings, and text to be left justified (see § 201.66(d) and (d)(4)). The regulation also requires the use of horizontal barlines and hairlines — extending to each side of the Drug Facts box — to provide separation between headings and subheadings (see § 201.66(d)(8)). These requirements contribute to the overall organization of the information, provide the user with easy and consistent access to required information, and help maximize the amount of open space within the Drug Facts box. More open space (i.e., space not occupied by text) generally contributes to greater readability.

The rule, however, can accommodate the use of more than one Drug Facts box on each side of a package container, or the use of side-by-side Drug Facts boxes on a wrap-around label (e.g., the label of a bottle of cough syrup). Such a presentation generally is consistent with the rule, provided it is done in a manner that allows for the clear and legible presentation of all required labeling information. In the case of elongated packages (such as toothpaste and topical ointment packages), the column format may noticeably improve readability.

The following recommendations should be helpful if you are considering the use of columns in OTC drug product labeling.

- If you are using two or more Drug Facts boxes on the same side of a package, the first Drug Facts box or column should be left justified and should bear the title "Drug Facts." The right side of the first column and the left side of the second column (and the right side of the second column and the left side of the third column, if a third column is used), may share a common vertical barline extending to each end of the Drug Facts box.

- When multiple Drug Facts boxes or columns appear on the same side of container, the

columns should be approximately the same size. All subsequent columns on the same side of the container or on another side of the container should bear the title "Drug Facts (continued)" at the top of the column. A visual graphic (e.g., an arrow) should be used at the bottom of each column to signal continuation of the Drug Facts labeling to the next column.

- When using more than one Drug Facts box or column, subsequent boxes or columns should begin with a heading or subheading (after the appropriate title, i.e., Drug Facts or Drug Facts (continued)).

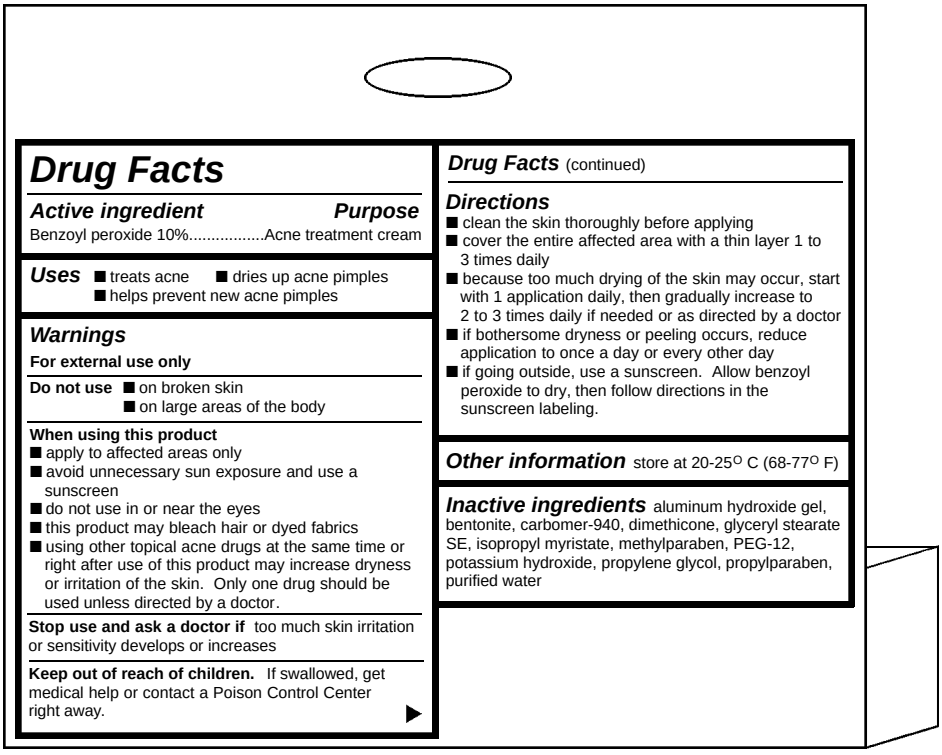
- Section 201.66(d)(6) requires "active ingredient" information to be left justified, and the corresponding "purpose" information to be right justified. Also, the rule requires that this information be presented in a manner that readily associates each active ingredient with its purpose. Accordingly, when multiple Drug Facts boxes or columns are used, it is important that the columns be wide enough to allow the active ingredient and purpose information to appear on the same horizontal line.

- The continuation of the required labeling onto multiple Drug Facts boxes or columns must be done in a manner that retains the order and flow of headings, subheadings, and information, as required under section 201.66, and meets all other requirements of section 201.66.

IV. COLUMNS UNDER THE MODIFIED LABELING FORMAT

When the Drug Facts labeling requires more than 60 percent of the total surface area available to bear labeling, the regulation provides that the box or similar enclosure required in section 201.66(d)(8) may be omitted if the Drug Facts labeling is set off from the rest of the labeling by use of color contrast (§ 201.66(d)(10)(v)). In such a case, if more than one Drug Facts box or column is used on the same side of a package, or side-by-side on a wrap-around label, the columns should be separated by adequate vertical common space of a contrasting color. Barlines and hairlines should begin and end where the text begins and ends and should not extend into the common space between the columns.

Figure 1. Drug Facts in Columns
Standard Labeling Format
Package with Carton Riser



Drug Facts

Active ingredient ***Purpose***

Benzoyl peroxide 10%.....Acne treatment cream

Uses ■ treats acne ■ dries up acne pimples ■ helps prevent new acne pimples

Warnings

For external use only

Do not use ■ on broken skin ■ on large areas of the body

When using this product
- apply to affected areas only
- avoid unnecessary sun exposure and use a sunscreen
- do not use in or near the eyes
- this product may bleach hair or dyed fabrics
- using other topical acne drugs at the same time or right after use of this product may increase dryness or irritation of the skin. Only one drug should be used unless directed by a doctor.

Stop use and ask a doctor if too much skin irritation or sensitivity develops or increases

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. ▶

Drug Facts (continued)

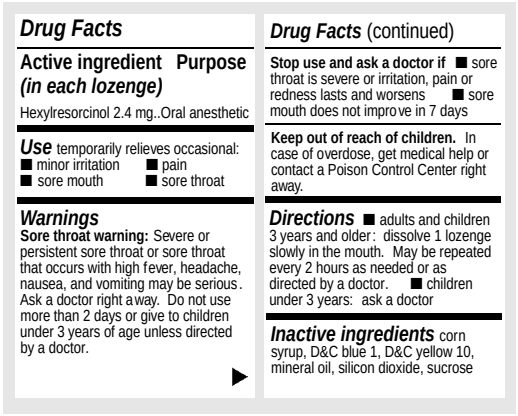
Directions
- clean the skin thoroughly before applying
- cover the entire affected area with a thin layer 1 to 3 times daily
- because too much drying of the skin may occur, start with 1 application daily, then gradually increase to 2 to 3 times daily if needed or as directed by a doctor
- if bothersome dryness or peeling occurs, reduce application to once a day or every other day
- if going outside, use a sunscreen. Allow benzoyl peroxide to dry, then follow directions in the sunscreen labeling.

Other information store at 20-25^{O} C (68-77^{O} F)

Inactive ingredients aluminum hydroxide gel, bentonite, carbomer-940, dimethicone, glyceryl stearate SE, isopropyl myristate, methylparaben, PEG-12, potassium hydroxide, propylene glycol, propylparaben, purified water

* Note: 14 point Helvetica Bold Italic Title
8 point Helvetica Bold Italic Headings
6 point Helvetica Bold Subheadings
6 point Helvetica Regular Text
7 point Leading

Figure 2. Drug Facts in Columns
Modified Labeling Format



Drug Facts

Active ingredient (in each lozenge) **Purpose**

Hexylresorcinol 2.4 mg. . Oral anesthetic

Use temporarily relieves occasional:
■ minor irritation ■ pain
■ sore mouth ■ sore throat

Warnings

Sore throat warning: Severe or persistent sore throat or sore throat that occurs with high fever, headache, nausea, and vomiting may be serious. Ask a doctor right away. Do not use more than 2 days or give to children under 3 years of age unless directed by a doctor.

▶

Drug Facts (continued)

Stop use and ask a doctor if ■ sore throat is severe or irritation, pain or redness lasts and worsens ■ sore mouth does not improve in 7 days

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions ■ adults and children 3 years and older: dissolve 1 lozenge slowly in the mouth. May be repeated every 2 hours as needed or as directed by a doctor. ■ children under 3 years: ask a doctor

Inactive ingredients corn syrup, D&C blue 1, D&C yellow 10, mineral oil, silicon dioxide, sucrose

* Note: 9 point Helvetica Narrow Bold Italic Title
8 point Helvetica Narrow Bold Italic Headings
6 point Helvetica Narrow Bold Subheadings
6 point Helvetica Narrow Text
6 point Leading

Box barline omitted; color contrast used to highlight Drug Facts information